



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:

McKENZIE et al.

Serial No.: 09/163,089

Filed: September 29, 1998

Atty. File No.: 4102-1

For: "COMPOSITIONS FOR
IMMUNOTHERAPY AND USES
THEREOF"

Commissioner for Patents
Washington, D.C. 20231

Group Art Unit: 1645

Examiner: Zeman, R.

RESPONSE TO
RESTRICTION REQUIREMENT

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SHERIDAN ROSS P.C.

BY: *Kathleen Russell*

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Dear Sir:

This response is filed in response to a third Restriction Requirement having a mailing date of June 8, 2001. Enclosed herewith is a request for a one month extension of time, with the requisite fee, to extend the time for responding from July 8, 2001 to August 8, 2001. No additional fees are believed to be due in connection with this response, but in the event that fees are due, please debit Deposit Account No. 19-1970.

The Examiner has withdrawn the finality of the last Office Action and has issued a new Restriction Requirement. The claims have been restricted as follows: Group I (Claims 1, 3-17, 19-21, 24-26, 38 and 70), drawn to an immunoregulatory composition comprising mannose receptor-bearing cells, a polymer of fully oxidized mannose, biological response modifiers and an antigen; Group II (Claims 1, 3-7, 12-17, 19-21, 26, 38 and 70), drawn to an immunoregulatory composition comprising mannose receptor-bearing cells, a polymer of fully oxidized mannose and an antigen; Group III (Claims 1-17, 19-22, 24-26, 38 and 70), drawn to an immunoregulatory composition comprising mannose receptor-bearing cells, a polymer of partially reduced mannose, biological response modifiers, and an antigen; Group IV (Claims 1-7, 12-17, 19-22, 26, 38 and 70), drawn to an immunoregulatory composition comprising mannose receptor-bearing cells, a polymer of partially reduced mannose and an antigen; Group V (Claims 27-37), drawn to immunoregulatory mannose

receptor-bearing cells; and Group VI (Claims 39-46 and 48-51), drawn to methods of obtaining immunoregulatory mannose receptor-bearing cells.

Applicants provisionally elect to prosecute the claims of Group I (1, 3-17, 19-21, 24-26, 38 and 70), with traverse.

Applicants traverse the Examiner's restriction between Groups I-VI. The Patent Office may require restriction if two or more "independent and distinct" inventions are claimed in one application. However, "if the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions." M.P.E.P. Section 803. Applicants submit that a thorough search for Group I should also include the subject matter of Groups II-V, and that Group VI is a method of making the product of the claims of Groups I-V, and therefore, should be rejoined with these groups, as discussed below. In general, in the present case, the subject matter of these Groups cited by the Examiner is sufficiently small and is so closely related as to be capable of examination together. Indeed, it is emphasized that Applicants have already been through two rounds of prosecution for the pending claims, and that there are no prior art issues currently outstanding in the application. The restriction requirements in this case only serve to increase the prosecution expense to the Applicants and to the Patent and Trademark Office, which is especially true in this application, since this is the third Restriction Requirement to be issued, the first and third of which were made by the same Examiner.

More specifically, Applicants traverse the restriction between Groups I and II and between Groups III and IV, on the basis that the claims which recite a biological response modifier are further embodiments of the claims without such modifier. For example, Claim 1 does not require the presence of a biological modifier, which appears in a *dependent* claim (Claim 8). Therefore, If the Examiner performs a search of the invention including cells with a biological modifier as Applicants have elected, then logically, cells without a biological modifier are simultaneously searched and there is no additional burden on the Examiner. Applicants note that Claim 1 has already been searched and examined, and no art has been cited which relies on the presence of a biological modifier. To now require Applicants to file *four* applications, when it is not believed that a search of *at least* the combination of Groups I and II or the combination of Groups III and IV would require any additional burden, is believed to be inappropriate according to M.P.E.P. Section 803.

With regard to the restriction between Groups I-IV on the basis of whether a fully oxidized mannose or a partially reduced mannose is recited, Applicants submit that these subjects are so closely related (e.g., via the common feature of mannose) that a thorough search for mannose with regard to the present invention will be sufficient to examine both types of mannose. Applicants note that Claim 1 has already been searched and examined, and it is not believed that it would require an additional burden on the Examiner to reexamine all of the pending claims. Again, this argument is believed to be within the spirit of M.P.E.P. Section 803.

With regard to Group V, Applicants specifically traverse the separation of these claims from any of Groups I-IV. The claims of Group V are product-by-process claims that result in essentially the same composition as claimed in Claim 1, which is common between Groups I-IV. Applicants fail to see how a search and examination of any of Groups I-IV would not be sufficient to examine the cells claimed in Group V.

Finally, with regard to Group VI, Applicants traverse the Examiner's position that this method should be separated from Groups I-V because the Inventions of Groups I-IV can not be used in the method of Group VI. The invention of Group VI is effectively a method of making the inventions of Groups I-IV and therefore, it is believed that the Examiner could examine this method without undue burden. At a minimum, if the elected claims of Group I are found allowable, Applicants reserve their right to amend the claims of Group VI to be commensurate in scope with the product claims of Group I, and to request that such amended claims that depend from or otherwise include all the limitations of the allowable product be rejoined and examined for patentability. In re Brouwer, 37 USPQ2d 1663 (Fed. Cir. 1996); In re Ochiai, 37 USPQ2d 1127 (Fed. Cir. 1995).

The Examiner has also required an election of species between the antigens in Claim 12. Applicants provisionally elect to prosecute the species of MUC1, without traverse. With regard to the Examiner's species election requirement, Applicants note that such a requirement is primarily, if not solely, intended to facilitate a search by the Examiner. Applicants note that the Examiner is obligated to examine the generic claims and submits that the scope of the claims of the present invention is not limited to the elected species.

In view of the foregoing discussion, Applicants respectfully request that the Examiner withdraw the restriction requirement between Groups I-VI.

Respectfully submitted,

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